

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

THIS DOCUMENT RELATES TO ALL
CLASS ACTIONS

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

PLAINTIFFS' MEMORANDUM IN SUPPORT OF
MOTION TO COMPEL COMPLIANCE WITH CMO NO. 7 AGAINST DEFENDANTS
ABBOTT, DEY, PHARMACIA, SHERING-PLOUGH AND WARRICK

On August 15, 2003 the Court issued CMO No. 7 that provided in part as follows:

II. Allowed Discovery Pending Decision on Motions to Dismiss

1. Plaintiffs shall conduct discovery on claims set forth *against a defendant named in the MCC that was not dismissed as to both Class 1 and Class 2 claims.* The specific drugs subject to discovery are those identified in the defendant-specific allegations of the MCC if the MCC identified a specific plaintiff who purchased the drug. There shall be no discovery on multi-source drugs.

3. *All non-dismissed defendants are directed to supplement their document productions* under the order of this Court dated October 28, 2002 (relating to production of documents produced to governmental bodies concerning AWP matters) by producing all documents produced by a non-dismissed defendant in response to recent subpoenas issued by the House Energy and Commerce Committee, or any other governmental body, by making such documents available to counsel for the plaintiffs for inspection and photocopying within 30 days. (Emphasis added.)

Defendants Abbott, Dey, Pharmacia, Schering-Plough and Warrick received a letter from the U.S. House Committee on Energy and Commerce on June 26, 2003 requesting the production of documents relating to AWP issues. See News Release from the Committee on Energy and Commerce attached hereto as Exhibit A.

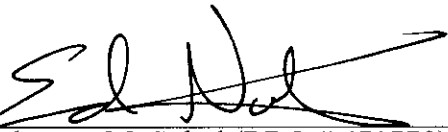
These Defendants were not dismissed from Class 2 of the Master Consolidated Class Action Complaint (the "MCC"). See *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 263 F. Supp. 172, 195 (D. Mass. 2003).

These Defendants have not complied with CMO No. 7 that requires production to Plaintiffs of documents produced to the House Energy and Commerce Committee by non-dismissed Defendants. Instead each of these Defendants has taken the position that as manufacturers of multi-source drugs they were dismissed from the MCC. See correspondence from Defendants attached hereto as Exhibit B. Plaintiffs believe that Section II, ¶3 of CMO 7 applies to Defendants not "dismissed as to both Class 1 and Class 2 claims." None of these Defendants were dismissed from both Classes of the MCC, hence ¶ 3 of CMO No. 7 applies despite the fact that elsewhere, discovery on multi-source drugs is not permitted by CMO No. 7.

Plaintiffs hereby request that the Court enter an Order requiring each of Defendants Abbott, Dey, Pharmacia, Schering-Plough and Warrick comply with CMO No. 7 and supplement their production to Plaintiffs accordingly. Plaintiffs have filed herewith a Proposed Order for the Court's consideration.

Respectfully Submitted,

DATED: September 17, 2003

By 

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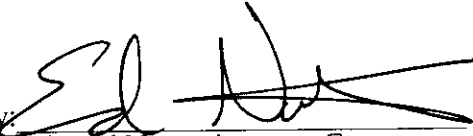
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**ADDITIONAL ATTORNEYS FOR
PLAINTIFFS**

CERTIFICATE OF SERVICE

I hereby certify that I, Edward Notargiacomo, an attorney, caused true and correct copies of the foregoing Plaintiffs' Memorandum in Support of Motion To Compel Compliance With CMO No. 7 Against Defendants Abbott, Dey, Pharmacia, Shering-Plough and Warrick to be served on all counsel of record electronically, pursuant to Section D of Case Management Order No. 2., this 17th day of September, 2003.

By: 
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Committee Correspondence

The Committee on Energy and Commerce
W.J. "Billy" Tauzin, Chairman

Tauzin, Greenwood Expand Medicaid Fraud Investigation

WASHINGTON (June 26) - As part of an expanded investigation into Medicaid fraud, House Energy and Commerce Committee Chairman Billy Tauzin (R-LA) and Oversight and Investigations Subcommittee Chairman James Greenwood (R-PA) today sent letters to the following 26 drug companies:

Abbott Labs, Abbott Park, IL;
Alpharma, Fort Lee, NJ;
Apotex, Weston, Ontario, Canada;
Aventis Pharmaceuticals, Bridgewater, NJ;
Barr Labs, Pomona, NY;
Bristol Myers, New York, NY;
Dey, Napa Valley, CA;
Ethex, St. Louis, MO;
Eli Lilly, Indianapolis, IN;
Geneva, Princeton, NJ;
GlaxoSmithKline, Philadelphia, PA;
IVAX, Miami, FL;
Johnson & Johnson, New Brunswick, NJ;
Mylan Pharmaceuticals, Morgantown, WV;
Par Pharmaceuticals, Spring Valley, NY;
Pfizer, New York, NY;
Pharmacia, sub of Pfizer, New York, NY;
Purdue Pharma, Stamford, CT;
Purepac, Elizabeth, NJ;
Roche, Nutley, NJ;
Roxane, Columbus, OH;
Schering-Plough, Kenilworth, NJ;
TEVA, North Wales, PA;
UD Labs, Rockford, IL;
Warrick Pharmaceuticals, sub of Schering-Plough, Kenilworth, NJ; and
Watson, Carona, CA.

Below is the text of the letter.

June 26, 2003

The Committee on Energy and Commerce is conducting an investigation into pharmaceutical reimbursements and rebates under Medicaid. This inquiry builds upon the earlier work by this Committee on the relationship between the drug pricing practices of certain pharmaceutical companies and reimbursement rates under the Medicare program. In that investigation, the Committee uncovered significant discrepancies between what some pharmaceutical companies charged providers for certain drugs and what Medicare then reimbursed those providers for dispensing those drugs. This price difference resulted in profit incentives for providers to use the drugs of specific companies as well as higher costs to the Medicare system and the patients it serves. For example, we learned that one manufacturer sold a chemotherapy drug to a health care provider for \$7.50, when the reported price for Medicare was \$740. The taxpayer therefore reimbursed the doctor almost \$600 for dispensing the drug and the cancer patient had a \$148 co-payment. Such practices are unacceptable in the view of the Committee, which is why we are in the process of moving legislation to address these abuses.

The Committee has similar concerns regarding drug prices in Medicaid, which has a substantially larger pharmaceutical benefit than Medicare. For this Medicaid investigation, we have chosen to review pricing and other aspects relating to

certain drugs produced by your company, along with a fairly large group of other drugs and manufacturers, based upon several indicia from a number of sources, including utilization data, drug price/reimbursement spreads, and other relevant information.

In order for this Committee to effectively and efficiently conduct this review, we are requesting that, pursuant to Rules X and XI of the U.S. House of Representatives, you provide the Committee with the following records and information by July 11, 2003. For the purposes of these requests, please observe the following definitions: "subject drugs" means: acyclovir, amikacin sulfate, furosemide, gentamicin sulfate, paclitaxel, tobramycin sulfate, and vancomycin, in all dosages, strengths or volumes, and regardless of any packaging, labeling or identifiers; "purchaser" means any wholesaler, distributor, retailer, provider, doctor, hospital, pharmacy, health maintenance organization, or any other such entity that obtains the subject drugs at any cost, including free of charge; "spread" means the difference between the cost of the drug to the purchaser and the reimbursement amount the purchaser may receive from any State's Medicaid program, including, but not limited to, (1) the difference between the cost or price to the purchaser and the actual or anticipated Medicaid reimbursement or, (2) the difference between the cost or price to the purchaser and any price or cost submitted, or caused to be submitted by the drug's manufacturer, to any State, Federal agency or Medical Economics Red Book, First Data Bank or Medi-Span or any other such entity that gathers and publishes drug cost or pricing data, such as "average wholesale price," or "wholesale acquisition cost"; and "net revenue" means revenue received from the sale of subject drugs after subtracting any discounts, rebates, charge-backs or any other such price concession, paid by you to any purchaser.

Further, for the purposes of responding to these requests, where providing records or information, please separate and distinguish such records or information, to the extent possible, by each applicable National Drug Code ("NDC") and Healthcare Common Procedural Coding System code. Also, for the purposes of responding to these requests, please do not produce any specific patient medical information. Finally, please note that these requests are directed to your company and any and all related corporate entities that may have responsive documents or information, including, but not limited to, any parents, subsidiaries, partnerships, or joint ventures.

1. For the period beginning January 1, 1998, and for each subsequent calendar quarter, and with respect to each of the subject drugs, please provide the following information using the format of the chart below:
 - a. the total volume of sales, indicating both the number of units and net revenue;
 - b. the "average wholesale price" (AWP), as reported in Medical Economics Red Book, First Data Bank and/or Medi-Span, and the volume of sales (in both units and net revenue) occurring (i) at or within five percent of AWP, whether higher or lower, (ii) at more than five percent above AWP, and (iii) at more than five percent below AWP;
 - c. the "average manufacturer price" (AMP), as reported to the Secretary of Health and Human Services, pursuant to the requirements of Social Security Act ("SSA") §1927(b)(3), and the volume of sales (in both units and net revenue) occurring (i) at AMP and up to and including 10 percent above AMP, and at below AMP but less than or equal to 10 percent below AMP (broken out separately), (ii) at greater than 10 percent above AMP but less than or equal to 20 percent above AMP, and at greater than 10 percent below AMP but less than or equal to 20 percent below AMP (broken out separately), (iii) at greater than 20 percent above AMP but less than or equal to 30 percent above AMP, and at greater than 20 percent below AMP but less than or equal to 30 percent below AMP (broken out separately), (iv) at greater than 30 percent above AMP but less than or equal to 40 percent above AMP, and at greater than 30 percent below AMP but less than or equal to 40 percent below AMP (broken out separately), and (v) at greater than 40 percent above AMP but less than or equal to 50 percent above AMP, and at greater than 40 percent below AMP but less than or equal to 50 percent below AMP (broken out separately);
 - d. the "wholesale acquisition cost" (WAC), as reported by Medical Economics Red Book, First Data Bank and/or Medi-Span or any other such entity that gathers and publishes "wholesale acquisition costs," and the volume of sales (in both units and net revenue) occurring (i) at or within five percent of WAC, whether higher or lower, (ii) at more than five percent above WAC, and (iii) at more than five percent below WAC;
 - e. the "best price," as reported to the Secretary of Health and Human Services, pursuant to the requirements of SSA §1927(b)(3), and the volume of sales (in both units and net revenue) occurring (i) at or within five percent of the best price, whether higher or lower, (ii) at more than five percent above best price, and (iii) at more than five percent below best price (if applicable);

- f. the total volume of sales, in both the number of units and net revenue, exempted from the calculation of the Medicaid best price as "merely nominal in amount," pursuant to the requirements of SSA §1927(c)(1)(C)(ii)(III);
- g. the average price of the "nominal" sales, referenced in subsection (f), above; and
- h. the total volume of the subject drug, in units, distributed as free goods.

NDC And J- Code	Quarter	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)
	1Q98	Total					Total		
	2Q98	volume	AWP	AWO	WAC	Best	volume of	Avg. price of	Total volume of
	3Q98	of sales				Price	sales at	sales at	subject drug
	etc.						"nominal	"nominal"	distributed as
							price"	price	free goods.

- 2. For the period beginning January 1, 1998, and for each subsequent calendar quarter, and with respect to each of the subject drugs, please provide the following information:
 - a. a. the total volume of the subject drug, in units and net revenue, distributed under state Medicaid programs;
 - b. b. the average per unit rebate issued for the subject drug; and
 - c. c. the total amount of rebates, in dollars, issued to state Medicaid programs with respect to the subject drug.
- 3. 3. For the period of January 1, 1998, to the present, please provide all records relating to any perceived or actual failure of any State to seek or achieve full rebates for the subject drugs dispensed under its state Medicaid system.
- 4. 4. For the period beginning January 1, 1998, to the present, has the distribution, marketing, sales or promotion of any subject drug considered, incorporated, or been based upon, in any way, the spread? If so, please describe the circumstances of such distribution, marketing, sales or promotion, and provide all records relating thereto.
- 5. 5. For the period beginning January 1, 1998, to the present, please provide all records relating to the spread on the subject drugs.
- 6. 6. For the period of January 1, 1998, to the present, please provide all records relating to comparisons between the spread of any subject drug and the spread of any generic or therapeutically equivalent product.
- 7. 7. For the period of January 1, 1998, to the present, please provide all records relating to the distribution, marketing, sales or promotion of any subject drug at prices exempted from the calculation of the Medicaid "best price," pursuant to the requirements of SSA §1927(c)(1)(C)(ii)(III), including, but not limited to, distribution, marketing, sales or promotion of the subject drug at "nominal price" or otherwise as free product, free goods, or at no cost.
- 8. 8. For the period of January 1, 1998, to the present, please state for each calendar quarter the largest single purchaser, in terms of units, of each of the subject drugs and the following:
 - a. a. the total number of units of the subject drug received by that purchaser; and
 - b. b. the total net revenue received for the subject drug by your company from that purchaser.

Please also provide the contract or agreement governing your relationship with that purchaser for each relevant quarter.

- 9. For the period of January 1, 1998, to the present, and for each subject drug, please provide a list of all purchasers who received the subject drug at a price exempted from the calculation of the Medicaid "best price," pursuant to the requirements of SSA §1927(c)(1)(C)(ii)(III), and, for each such purchaser, indicate the volume of the subject drugs received by calendar quarter, in units, and the range of prices at which such purchaser received the subject drug for that quarter.
- 10. Please state the date of expiration for any patents on the subject drugs.
- 11. Please describe how you define, interpret and/or calculate "prices that are merely nominal in amount," as set forth

- in SSA §1927(c)(1)(C)(ii)(III).
12. With respect to each subject drug, please describe how you calculate the prices and/or data reported to Medical Economics Red Book, First Data Bank or Medi-Span or any other such entity that gathers and publishes either "average wholesale prices" or "wholesale acquisition costs."
 13. For the period of January 1, 1998, to the present, please provide all records relating to the "average wholesale price" or "wholesale acquisition cost" of any subject drug that was submitted to Medical Economics Red Book, First Data Bank or Medi-Span or any other such entity that gathers and publishes "average wholesale prices" and/or "wholesale acquisition costs."
 14. For the period of January 1, 1998, to the present, please provide all records relating to any proposed, considered or implemented change in the "average wholesale price" or "wholesale acquisition cost" of any subject drug.

Please note that, for the purpose of responding to the above requests, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. If you have any questions, please contact Mr. Mark Paoletta, Chief Counsel for Oversight and Investigations, at (202) 225-2927.

Sincerely,

W.J. "Billy" Tauzin Chairman

James C. Greenwood Chairman Subcommittee on Oversight and Investigations

cc: The Honorable John D. Dingell, Ranking Member The Honorable Peter Deutsch, Ranking Member Subcommittee on Oversight and Investigations

Attachment

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

Related Documents

Health
Oversight and Investigation

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September 13, 2003

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Re: In re Average Wholesale Pricing Litigation, MDL No. 1456

Dear Mr. Berman:

We represent Abbott Laboratories. I write in response to your letter of September 10, 2003 regarding production of documents pursuant to paragraph 3 of case management order number 7. As you are aware, the Court's May 14, 2003 Order dismissed all claims asserted by your clients against Abbott. Accordingly, Abbott is a dismissed defendant with respect to the Master Consolidated Complaint and is not obligated to produce documents to you under paragraph 3 of case management order number 7.

Yours very truly,

Robert Christopher Cook

cc: All Counsel of Record (via Verilaw)



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September 15, 2003

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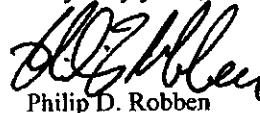
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Re: In re Pharmaceutical Indus. Average Wholesale Price Litig.,
MDL No. 1456 (D. Mass.)

Dear Mr. Berman:

This firm represents defendant Dey, Inc. ("Dey"). I have your letter dated September 10, 2003, regarding section 11.3 of Case Management Order No. 7. In response to your September 10 letter, I refer you to my letter to you, dated August 22, 2003, which addresses the issues you raise. A copy my August 22 letter is attached.

Very truly yours,



Philip D. Robben

PDR:nas

cc: All Counsel of Record (Via Verilaw)

NY01/ROBBP/863620.1



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Re: In re Pharmaceutical Indus. Average Wholesale Price Litig.,
MDL No. 1456 (D. Mass.)

Dear Mr. Berman:

This firm represents defendant Dey, Inc. ("Dey"). I have your letter addressed to Scott Wise, dated August 11, 2003, regarding discovery in this action and write in response thereto.

Your August 11 letter contends that, pursuant to Section II.3 of CMO No. 7, Dey is required to produce "discovery consisting of material produced in response to the House Energy and Commerce Committee or any governmental agency within thirty days." This interpretation of CMO No. 7 is erroneous. Dey will not be producing the referenced documents.

Section II.3 of CMO No. 7 is expressly limited to "non-dismissed defendants". This category does not include Dey, which was fully dismissed from this action on May 13, 2003. *See In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 263 F. Supp.2d 172, 195 (D. Mass. 2003) ("I allow the motion to dismiss all multi-source generic drugs from the complaint . . ."). As you are aware – and your August 11 letter and attached chart implicitly concede – all of the Dey drugs at issue in the MCC were multiple-source drugs. As such, Dey was dismissed by the May 13, 2003, order, and Dey is not obligated to produce any of the documents set forth in Section II.3 of CMO No. 7.

Very truly yours,

Philip D. Robben

PDR:nas

cc: All Counsel of Record (Via Verilaw)

NY01/ROBBP/859589.1